REMARKS:

The Official Action of January 9, 2009, and the prior art relied upon therein has been carefully studied. The claims in the application remain as claims 1-10 and 34-47, and the Applicant respectfully submits and maintains that these claims define both novel and unobvious subject matter under Sections 102 and 103, thereby warranting their allowance. Applicant, therefore, respectfully requests favorable reconsideration and allowance.

Claims 1, 10, 34-41 and 43 have been rejected as obvious under Section 103 from U.S. Patent No. 6,283,934 (Borgesen '934) in view of newly-cited and applied U.S. Patent No. 6,585,677 (Cowan). This rejection is respectfully traversed.

Borgesen '934, an earlier patent of the present Applicant and previously relied upon and rebutted in Applicant's reply of November 5, 2008, is stated in the rejection as disclosing "the method substantially as claimed by Applicant." Respectfully, Applicant disagrees. Important differences have been pointed out, and they are respectfully repeated by reference.

Indeed, the PTO recognizes that Borgesen '934 does not anticipate any of Applicant's claims, and therefore the PTO rejects under Section 103 rather than Section 102 and relies on Cowan as a secondary reference. As best understood, Cowan is only relied upon for the purpose set forth in the paragraph spanning pages three and four of the Office Action, namely the use of an adhesion-resistant coating on a CSF shunt. But even if it were obvious to modify Borgesen '934 in view of Cowan to provide an adhesion-resistant coating on the Borgesen '934

shunt, the so-reconstructed Borgesen '934 would not correspond to the claimed method.

Thus, and briefly, such a so-reconstructed Borgesen '934 would not provide a method for shunting toxic substances in the CSF, bearing in mind that the CSF itself is not a toxic substance.

The so-reconstructed Borgesen '934 would not employ a shunt body comprised of a flow-restricting component capable of maintaining a passive and essentially constant resistance to flow of cerebrospinal fluids of less than 8 Hg/ml/min as previously called for in claim 10 and now called for in claim 1, because according to Borgesen '934 the resistance to flow is at least 8 Hg/ml/min, not less than 8 as herein claimed.

The so-reconstructed Borgesen '934 would not result in a method in which the specified toxic substances were shunted, and Applicant notes that claim 9 has not been rejected as obvious from Borgesen '934 in view of Cowan.

More generally, Borgesen '934 concerns drainage of cerebrospinal fluids (CSF) from the ventricles to the sinus system in patients with increased intracranial pressure (ICP). When the ICP is increased, the pressure of the ventricles is also increased while the pressure in the sinus system is normal. Thus, the pressure difference between the ventricles and the sinus system is increased and it is necessary to use a relatively high flow resistance in the range of at least 8 Hg/ml/min in order to avoid over-drainage of CSF as a consequence of the increased pressure difference. This is what Borgesen '934 discloses and teaches.

The present invention involves the drainage of CSF under quite different conditions. For example, in Alzheimer's

disease the ICP is always or almost always normal.[1] Because the ICP is normal, the pressure difference between the ventricles and the sinus system in the present invention is also normal, and therefore the shunt system with a low resistance to flow, as claimed, is to be used for drainage of CSF from the ventricles to the sinus system in such cases, according to the present invention.

There is nothing in either Borgesen '934 or Cowan, and therefore nothing in any possible combination of these documents which would or could lead the person of ordinary skill in the art to provide a resistance to flow of less than 8 Hg/ml/min, or even lower such as set forth in claim 10.

Applicant accordingly wishes to strongly emphasize that neither Borgesen '934 or Cowan relates to or discloses anything about the conditions treated according to the present invention, e.g. Alzheimer's disease, or the presence of toxic substances within the CSF. To the contrary, both references deal primarily with the treatment of hydrocephalus which is not linked or related to Alzheimer's disease. Thus, the individuals treated by the claimed method are different individuals from those treated according to Borgesen '934 and Cowan, and neither of those references would have made it obvious to person of ordinary skill in the art to treat individuals of the character called for in claim 1.

Withdrawal of the rejection is in order and is respectfully requested.

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[1] In a few patients, both increased ICP and Alzheimer's might and perhaps probably exist, but this is still subject to heated scientific debate, and is irrelevant to the claimed method which does not concern any such cases which might exist with increased ICP.

Applicant wishes to raise one additional point with respect to statements appearing in the penultimate and ultimate sentences of the penultimate paragraph on page three of the Office Action. Here the rejection states as follows:

> Borgesen ['934] necessarily performs all the steps claimed by Applicant. Accordingly, there is no patentable difference between the method claimed by Applicant and the method disclosed by Borgesen ['934]. (Bracketed material added)

For reasons already stated above, Applicant respectfully but strongly disagrees. Borgesen '934 certainly does not perform the recited steps in conjunction the individuals specified in Applicant's claims. And the above-quoted statement implies the existence of inherency. But there is no evidence of inherency and there is no inherency.

Claims 1, 10 and 34-37 have been rejected under Section 102 as anticipated by U.S. Patent Application Publication No. 2002/0045847 (Borgesen '847), now issued as U.S. Patent No. 6,905,474. This rejection is respectfully traversed.

At the outset, there is some confusion in the rejection. As is clearly stated at the beginning of paragraph three on page five of the Office Action, the rejection is under Section 102 based on Borgesen '847. On the other hand, in the bottom paragraph on page six, in the same rejection, the Examiner appears to rely on Cowan as a secondary reference. If Cowan is relied upon as a secondary reference, the rejection cannot be under Section 102. Applicant respectfully traverses the rejection whether it is based on Section 102 on Borgesen

'847 alone or under Section 103 based on Borgesen '847 in view of Cowan. However, the record should be clarified.

Borgesen '847 concerns drainage of CSF from the ventricles to the sinus system in patients with a normal ICP but with a pathologically increased volume of CSF in the ventricles, i.e., normal pressure hydrocephalus. In this situation, the pressure difference between the ventricles and the sinus system is "normal". Such "normal" pressure difference is relatively quite low, and so the risk of over-drainage is therefore minimal. Because of the low risk of over-drainage, a low resistance to flow, e.g. below 8 Hg/ml/min, can be used.

Nevertheless, Borgesen '847 does not disclose and does not teach the specifically claimed method of CSF toxic components from an individual whose CSF contains such toxic components. Applicant respectfully notes that Applicant's claims are directed to a method, not an apparatus.[2]

Cowan adds no more to Borgesen '847 than it does to Borgesen '934, and thus the comments made above with respect to the proposed combination of Borgesen '934 in view of Cowan apply equally here, and are therefore respectfully repeated by reference.

In this rejection, as in the previous one, inherency has been implied at the end of the second paragraph at page six of the Office Action. Respectfully, there is no basis for any such inherency. The individual treated by the claimed method is different. The condition suffered by that individual is different. And in the present invention, the CSF contains toxic components which are not inherently present in the CSF of

[2] The apparatus of Borgesen '847 may be useable in the presently-claimed method, and the method of Borgesen '847 may be dominant but Borgesen '847 still does not disclose and does not make obvious the presently-claimed method.

hydrocephalus patients. The law is clear that for inherency to exist, such inherency must be reasonably certain, and such a situation does not exist in the present case.

Withdrawal of the rejection is respectfully requested.

Claims 2-9 have been rejected as obvious under Section 103 from either Borgesen '934 or Borgesen '847, either in view of Cowan and further in view of Saul et al. U.S. Patent No. 6,383,159 (Saul). These rejections are respectfully traversed.

Claims 2-9 depend from and incorporate the subject matter of claim 1, and thus define patentable subject matter over Borgesen '934 in view of Cowan, and over Borgesen '847 in view of Cowan, for the reasons pointed out above with respect to the claim 1 part of claims 2-9. Saul is relied upon as disclosing removal of CSF from patients not suffering from hydrocephalus wherein the CSF contains toxic or pathogenic substances, e.g. in the treatment of Alzheimer's disease. The question which then arises is whether or not it would have been obvious to the person of ordinary skill in the art at the time the present invention was made to modify Borgesen '934 or Borgesen '847 by anything taught by Saul; and, if so, what type of modification would arise.

Applicant respectfully submits that Saul is incompatible with Borgesen '934 and Borgesen '847, and therefore the proposed combination would not have been obvious; and, in

particular, if one attempted to modify Borgesen '934 or Borgesen '847 in view of Saul, following what Saul requires and without flying in the face of Saul, what one would achieve is quite different from what is claimed.

In particular, both Borgesen '934 and Borgesen '847 relate to shunts with a constant resistance to flow (see, for example Column 4, lines 21-29 or Borgesen '934), whereas Saul concerns a shunt system with a pressure compensation involving a pressure-controlled variable resistance (Column 4, lines 21-36). The person of ordinary skill in the art cannot reasonably or obviously rely on Saul without using a pressure-controlled variable resistance, and that would be contrary to both Borgesen '934 and Borgesen '847, bearing in mind that variable resistance is a central aspect of Saul, while the contrary constant resistance is a central aspect of Borgesen '934 and Borgesen '847.

Moreover, to use what Saul demands and convert Borgesen '934 or Borgesen '847 to a variable resistance system, contrary to both Borgesen '934 or Borgesen '847, would also be contrary to the present invention, noting for example that the present application states that the prior art variable pressure, i.e. variable resistance, shunts cannot be used in the methods in the present invention (page 6, lines 26 through page 7, line 4).

This distinction is very important. The present invention concerns a method for shunting at a constant pressure difference between two compartments, in particular for shunting between two compartments within the head of the patient, namely the ventricles and the sinus (venous) system. The variable pressure (VP) shunt systems of the prior art, including that of Saul, are typically used to shunt between the ventricles and a compartment of the body not being in the head of the patient, e.g., the peritoneum or the heart. These shunts require a regulation of the resistance in the shunt in order to compensate for the variable pressure difference between the two compartments arising from, for example, the patient changing position from laying down to standing up. The bottom line is that VP shunt systems, including that of Saul, are fundamentally different from the present invention, and also from the systems of Borgesen '934 and Borgesen '847.

As a result, the combinations as proposed would not have been obvious. Withdrawal of the rejections is in order and is respectfully requested.

Applicant believes that all issues raised in the Official Action have addressed above in a manner which should lead to patentability of the present invention. Accordingly,

favorable reconsideration and early formal allowance are respectfully requested.

Respectfully submitted,

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